

Draft Package Insert

Howmedica Osteonics® ABC Ceramic on Ceramic Bearing System

Description

The Howmedica Osteonics® ABC System includes a ceramic-on-ceramic acetabular bearing couple and either the Howmedica Osteonics® PSL® MicroStructured® ABC Shells or the Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells. The bearing couple consists of an Howmedica Osteonics® Alumina C-Taper Head (28mm and 32mm) and an Howmedica Osteonics® Alumina Insert. In addition the system is intended to be used in conjunction with the press-fit Howmedica Osteonics® Omnifit –HA Hip Stems and Osteonics 6.5mm or 5.5mm bone screws cleared through the premarket notification process.

The Howmedica Osteonics® Alumina Inserts are assembled intraoperatively to the mating metal acetabular shell components via a taper locking mechanism. Some shells are designed to accept Osteonics® 6.5mm or 5.5 mm bone screws if additional fixation is necessary.

Materials:

- | | |
|--|--|
| • ASTM F-67 CP Titanium | Acetabular shell, Arc-deposited MicroStructured® coating |
| • ASTM F-1185 Hydroxylapatite | Hydroxylapatite powder |
| • ASTM F-603 Aluminum Oxide (Al ₂ O ₃) | Ceramic head, Ceramic insert |
| • ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE) | Acetabular bearing insert |
| • ASTM F-136 | Head Adaptor Sleeve |

Indications

- Painful, disabling joint disease of the hip resulting from: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant).

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity

Warnings

- Replace both the alumina insert and the acetabular cup if the insert is chipped, cracked, or otherwise damaged during the implant procedure or postoperative timeframe. This is because the acetabular shell taper, once it has been deformed through assembly to its mating ceramic insert, cannot be reassembled to another ceramic insert.
- Always ensure proper alignment and seating of the insert before final impaction to prevent chipping or damage. Improper seating of the insert may cause it to bind in the wrong position, chip or be damaged.
- Do not reassemble a ceramic head and stem or a ceramic insert and shell once they have been assembled due to the deformation incurred by the taper locking mechanisms during the initial assembly.

- Do not allow polished bearing areas and machined taper surfaces to come in contact with hard or abrasive surfaces, as scratching or in any way damaging these surfaces can significantly affect the structural integrity.
- Do not substitute another manufacturer's device for any of the Howmedica Osteonics® ABC System because design, material, or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together.
- Do not implant in obese patients because additional loading may lead to loss of fixation or device failure.
- Do not implant in patients undergoing revision of previously unsuccessful femoral head replacement, cup arthroplasty, or other procedure because the safety and effectiveness of these devices for indications other than non-inflammatory degenerative joint disease have not been established.
- Discard all damaged or mishandled implants. Never reuse an implant. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to early failure of the device.
- **Do not resterilize.** Return all packages with flaws in the sterile barrier to the supplier.

Precautions

- Clean bearing surfaces of debris prior to assembly as foreign particles may cause accelerated bearing wear, which may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Clean and dry machine taper surfaces to ensure proper seating and assembly.
- Do not handle the hydroxylapatite treated regions as it may compromise the sterility or integrity of the coating/implant interface.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load.
- Do not use a metal or zirconia head with the Howmedica Osteonics® Alumina Insert or the Trident™ Alumina Insert as this may accelerate bearing wear and lead to early failure of the device.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Avoid excessive verticalization of the shell which may accelerate bearing wear.

Adverse Events (Clinical Study)

Table 1 summarizes the adverse events reported for 349 cases implanted with the ABC System ceramic components (172 cases implanted with Howmedica Osteonics® PSL® MicroStructured® ABC Shells, referred to as ABC System I, and 177 cases implanted with the Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells, referred to as ABC System II) compared to 165 cases implanted with a control with a conventional polyethylene/metal bearing couple, evaluated out to 24 months postoperatively. Adverse events on an additional 114 'continued access' cases with data ranging up to 12 months postoperatively are also included in the these tables. Nine incidents of interoperative insert chipping were reported for the 349 investigational patients (2.6%), 6 for the 114 patients (5.3%) in the continued access population, and one for a patient from the continued access group who failed to meet the study inclusion criteria and is not included in Table 1, for a total of 16 incidents in 464 patients. The overall insert chipping rate for all patients implanted with the investigational components is 3.4%.

TABLE 1: Time Course Distribution of Operative Site Adverse Event Incidences for ABC System I¹ and ABC System II² vs. Control hip system out to 24 Months Post-Operatively.

| Operative Site Related | | ABC SYSTEM I ¹ (172 cases enrolled) | | | | | | ABC SYSTEM II ² (177 cases enrolled) | | | | | | CONT. ACCESS* (114 enrolled) | | | | | | CONTROL (165 cases enrolled) | | | | | |
|-------------------------|--|---|-----|-----|-----|-----|-----|--|-----|-----|-----|-----|-----|---------------------------------|-----|----|-----|-----|-----|---------------------------------|-----|-----|-----|--|--|
| | | io | ea | 6 | 12 | 24 | Tot | io | ea | 6 | 12 | 24 | Tot | io | ea | 12 | Tot | io | ea | 6 | 12 | 24 | Tot | | |
| Visit | | | | | | | | | | | | | | | | | | | | | | | | | |
| N = cases evaluated | | 172 | 170 | 166 | 168 | 131 | | 177 | 177 | 167 | 173 | 129 | | 114 | 113 | 77 | | 165 | 163 | 157 | 155 | 119 | | | |
| Revision: | | | | | 1 | | 1 | | | | | | | | | | | | 2 | | | | 2 | | |
| Femoral | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acetabular | | | | | | | | | 1 | | | | 1 | | | | | | | | | | 1 | | |
| Acetabular Insert | | | | | | | | | 1 | | | | 1 | | | | | | 2 | | | 2 | 4 | | |
| Femoral Head | | | | | 1 | | 1 | | 1 | | | | 1 | | | | | | 2 | | | 2 | 4 | | |
| All Components | | | | | | | | | | | 1 | | 1 | | | | | | | | | | | | |
| Femoral Fracture/Crack | | 6 | 3 | 1 | | | 10 | 7 | 2 | | | | 9 | 4 | | | 4 | 7 | 1 | 1 | | | 9 | | |
| Trochanteric Frac/Crack | | 4 | | | | | 4 | 3 | | | | | 3 | | | | | 1 | | | | | 1 | | |
| Acetabular Frac/Crack | | 2 | | | | | 2 | | | | | | | | | | | | | | | | | | |
| Loosening: Fem. Comp | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acetabular Comp | | | | | | | | | | | | | | | | | | | | | | | | | |
| Both Comp | | | | | | | | | | | | | | | | | | | | | | | | | |
| Superficial Infection | | | 1 | | | | 1 | | 4 | | | | 4 | | | | | | 5 | | | | 5 | | |
| Deep Joint Infection | | | | | | | | | | | 1 | | 1 | | | | | | 1 | | 1 | | 2 | | |
| Hematoma | | | 2 | | | | 2 | | | | | | | | 1 | | 1 | | 1 | | | | 1 | | |
| Wound Related | | | 8 | | | | 8 | | 8 | | | | 8 | | 4 | | 4 | 1 | 6 | | | | 7 | | |
| Dislocation: | | | 4 | | | | 4 | | 5 | | | | 5 | | 1 | | 1 | 1 | 3 | | | 1 | 5 | | |
| Single | | | | | | | | | | | | | | | | | | | | | | | | | |
| Recurrent | | | | | | | | | 1 | | | | 1 | | | | | | 1 | | 1 | | 2 | | |
| Nerve Palsy | | 1 | | | | | 1 | | 1 | | | | 1 | 1 | | | 1 | | | | | | | | |
| Subluxation | | | | | | | | | | | | | | | | | | | | 1 | | | 1 | | |
| Excessive Hip Pain | | 1 | 1 | | | | 2 | | | 1 | | | 1 | | | | | | | 2 | | | 2 | | |
| Bursitis | | | 1 | 1 | 2 | 1 | 5 | | | 4 | 4 | | 8 | | | 1 | 1 | | 1 | 1 | 3 | | 5 | | |
| Heterotopic bone | | | 3 | 2 | | | 5 | | 3 | 3 | | | 6 | | | | | | 6 | 4 | | | 10 | | |
| Subsidence | | | | 1 | | | 1 | | 2 | | | | 2 | | | | | | | | | | | | |
| Trochanteric non-union | | | | | | | | | | | | | | | | | | | | | | | | | |
| Soft Tissue Trauma | | | | 2 | 2 | 1 | 5 | | | 1 | 5 | | 6 | | 1 | | 1 | | 1 | 1 | 3 | | 5 | | |
| Chipping-Alumina Insert | | 5 ⁺ | | | | | 4 | 4 | | | | | 4 | 6 | | | 6 | | | | | | | | |
| Miscellaneous | | 2 | 5 | 3 | 2 | | 12 | 4 | 3 | 1 | 4 | | 12 | 2 | 2 | | 4 | 3 | 6 | 2 | 3 | 2 | 16 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| TOTAL | | 20 | 28 | 10 | 8 | 2 | 68 | 18 | 32 | 10 | 15 | 0 | 75 | 13 | 9 | 1 | 23 | 13 | 38 | 12 | 11 | 8 | 82 | | |

io = intraoperatively; ea = early (7 weeks); 6 = 6 months; 12 = 12 months; 24 = 24 months postoperative; Tot = total

All cases enrolled in the ABC I, ABC II, and Control groups had at least 12 months postoperative follow-up at time of data base closure.

*Includes 3 cases with ABC System I and 111 cases with ABC System II with up to 12 months postoperative follow-up at time of data base closure. A 6 month evaluation was not performed on these cases. Does not include data on one additional patient who was implanted, but failed to meet the study inclusion criteria. This patient experienced chipping of the ceramic insert during implantation.

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells.

+One patient had two incidents of insert chipping and both events are recorded here.

Other Potential Adverse Events

The following list includes other potential adverse events that may also occur and were either reported in the studies or are generally reported in the literature for total hip replacement procedures:

- Pulmonary embolism
- Circulatory compromise
- Vascular disorders, including thrombus
- Bronchiopulmonary disorders, including emboli
- Myocardial infarction
- Death
- Urinary tract infection
- Genitourinary disorders
- Gastrointestinal disorders
- Peripheral neuropathies
- Nerve damage
- Localized progressive bone resorption (osteolysis)
- Loosening of total hip components
- Pain due to loosening of the implant components.
- Metal sensitivity reactions
- Dermatologic disorders
- Carcinoma
- Heterotopic bone formation
- Reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb
- Breakage of the ceramic insert or ceramic head
- Disassembly of modular components at the taper junctions

Clinical Results

Two groups were studied. The first group consisted of a prospective, controlled, randomized, multi-center clinical trial. This study group consisted of 514 cases diagnosed with non-inflammatory degenerative joint disease (NIDJD) requiring a primary total hip replacement. Each subject was randomized to receive one of three possible shell/bearing combinations: either the ABC System I, the ABC System II (the Investigational Systems), or the control hip system (a conventional polyethylene/metal bearing couple) in a cementless application. Two year results for 280 Investigational cases (140 ABC I and 140 ABC II) and 133 Control cases were included in the data and are presented in this section. The second group consisted of 114 cases receiving the ABC System (3 ABC System I, 111 ABC System II) via continued access. Safety data for this group is reported in the form of adverse events in Table 1.

The following table provides a comparison of the demographics of those patients in the first group who received the ABC System I, ABC System II, and control hip system, respectively.

Table 2: Patient Demographics for ABC System Study Groups

| Category | ABC SYSTEM I | ABC SYSTEM II | CONTROL |
|--------------------|--------------|---------------|---------|
| No. Cases | 172 | 177 | 165 |
| Male/female | 114/58 | 113/64 | 99/66 |
| Mean Age (yrs.) | 53.1 | 53.1 | 53.3 |
| Mean Weight (lbs.) | 186.7 | 191.8 | 188.5 |
| Mean Height (ins.) | 68.6 | 68.2 | 68.4 |

The effectiveness of the Howmedica Osteonics® ABC System I and ABC System II was determined through the analysis of the Harris Hip Scores (HHS) and radiographic measurements. Table 3 compares the mean total Harris Hip Scores, and the percentage of cases with a minimum HHS of 70 and a Good/Excellent Rating of at least 80, as well as the radiographic success rates for the Investigational and Control groups, at two years postoperatively.

TABLE 3: Primary Efficacy Assessments for ABC System I and ABC System II vs. Control hip system. Efficacy assessment based on mean Harris Hip Score (HHS) and radiographic success reported for those cases with 2 year follow-up data.

| Primary Efficacy Assessment | ABC SYSTEM I 140 cases enrolled | ABC SYSTEM II 140 cases enrolled | CONTROL 133 cases enrolled |
|--|------------------------------------|-------------------------------------|-------------------------------|
| Preoperative mean HHS (range) | 49.6 (19.3 - 89.6) n=126 | 49.0 (24.7 - 75.2) n=131 | 49.3 (21.4 - 87.3) n=125 |
| 2 year postop mean HHS (range) | 96.3 (48.0 - 100) n=122 | 96.9 (56.9 - 100) n=120 | 95.1 (58.8 - 100) n=110 |
| % Excellent/Good Results (HHS 80-100 points) at 2 years postop | 95.9% (117/122) | 96.7% (116/120) | 93.6% (103/110) |
| % Total HHS \geq 70 at 2 years postop | 98.4% (120/122) | 99.2% (119/120) | 98.2% (108/110) |
| % Radiographic Success at 2 years postop | 100% (123/123) | 99.2% (121/122) | 100% (113/113) |

n = number of cases that had evaluable data

Table 4 summarizes the two year patient success rates as they relate to the success/failure criteria of study. For the purposes of the study, a patient was considered a success if they met all seven of the criteria identified in the table. Success for the study required that the patient success rates for the ABC System were no more than 7.5 percentage points worse than those of the control hip system and achieving complication rates that were statistically no worse than the control hip system at two years postoperatively.

TABLE 4: 2 Year Patient Success Rates

| Patient Success Criteria | ABC SYSTEM I 140 cases enrolled | ABC SYSTEM II 140 cases enrolled | CONTROL 133 cases enrolled |
|---|------------------------------------|-------------------------------------|-------------------------------|
| Absence of Revision (%) | 139 / 140 (99.3%) | 138 / 140 (98.6%) | 128 / 133 (96.2%) |
| Total HHS \geq 70 | 120 / 122 (98.4%) | 119 / 121* (98.4%) | 117 / 120** (97.5%) |
| Acetabular RLL \leq 2mm | 122 / 122 (100%) | 120 / 120 (100%) | 112 / 112 (100%) |
| Acetabular Migration \leq 3mm | 122 / 122 (100%) | 120 / 120 (100%) | 112 / 112 (100%) |
| Wear Acetabular Insert $<$ 0.5mm/yr | 122 / 122 (100%) | 120 / 120 (100%) | 112 / 112 (100%) |
| Femoral RLL \leq 2mm | 118 / 118 (100%) | 115 / 115 (100%) | 110 / 110 (100%) |
| Progressive Femoral Component Subsidence \leq 5mm | 122 / 122 (100%) | 119 / 120 (99.2%) | 111 / 111 (100%) |
| Patient Success Rate | 97.5% (118/121) | 95.8% (115/120) | 93.2% (110/118) |

* One case with HHS $<$ 70 at 12 months, and no 24 month follow-up and is included

** One case, with HHS $<$ 70 at 12 months, died before 24 month follow-up and is included

Sterilization

- These components have been sterilized by gamma radiation.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the

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presence of such a flaw, the product must be assumed nonsterile. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.

- Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
- If the package is opened, but the product is not used, the component **must not** be resterilized and must be discarded or returned to the supplier.
- **Do NOT autoclave ceramic heads or ceramic inserts, especially when they are affixed to their mating components. Differing expansion rates could cause ceramic to break or crack. Do NOT autoclave, and then rapidly cool, a ceramic component. Non-adherence to these warnings can permanently compromise the mechanical and structural integrity of the ceramic components.**

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

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Secur-Fit™ is a trademark of Howmedica Osteonics Corp.

Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677
A Division of Stryker Corporation.

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Draft Package Insert

Howmedica Osteonics® Trident™ Acetabular Component System and Howmedica Osteonics® Alumina Heads

Description

The Howmedica Osteonics® Trident™ System consists of a titanium alloy acetabular shell and the choice of any Trident™ acetabular bearing insert. The Trident™ System is available with a ceramic-on-ceramic acetabular bearing couple. The bearing couple consists of an Howmedica Osteonics® Alumina C-Taper Head (28mm, 32mm, and 36mm) and a Trident Alumina Insert. The Trident™ Alumina Insert features a pre-assembled titanium alloy sleeve. The insert is used in conjunction with the Trident™ AD with Pure-Fix HA Acetabular Shell and intended for cementless fixation within the prepared acetabulum. The Trident™ AD with Pure-Fix HA Acetabular Shell has also been cleared for use, through the premarket notification process, with the Trident™ UHMWPE inserts. The Trident™ UHMWPE inserts have been cleared for use, through the premarket notification process, with any Howmedica Osteonics® stem of compatible head size, with suitable stem size and style to achieve total reconstructive replacement of the hip joint.

The Howmedica Osteonics® Alumina C-Taper Heads may be used with either an Howmedica Osteonics® Trident™ UHMWPE acetabular insert or with an Howmedica Osteonics® Trident™ Alumina Insert.

If additional fixation is desired, the dome screw holes, if present, have been designed to accept Osteonics® 6.5mm or 5.5 mm bone screws. For the cups that have both dome and peripheral screw holes, Osteonics® 6.5mm bone screws must be used in the dome screw holes and Osteonics® 4.5 mm bone screws must be used in peripheral screw holes.

The dome and screw hole plugs are optional devices which are available to seal the Howmedica Osteonics® acetabular shell. The plugs are to be threaded into the dome holes of the shell.

Materials:

- | | |
|---|---------------------------------------|
| • ASTM F-620 Titanium 6Al-4V ELI Alloy | Acetabular Shell, Acetabular Insert |
| • ASTM F-136 | Head Adaptor Sleeves |
| • ASTM F-67 CP Titanium | Arc-deposited coating, Dome Hole Plug |
| • ASTM F-1185 Hydroxylapatite | Hydroxylapatite Powder |
| • ASTM F-603 Aluminum Oxide (Al ₂ O ₃) | Ceramic Head, Ceramic Insert |

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE)

Acetabular Bearing Insert

Indications

- Painful, disabling joint disease of the hip resulting from: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant).

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity

Warnings

- Do not reassemble a ceramic head and stem once they have been assembled due to the deformation incurred by the taper locking mechanisms during the initial assembly.
- Do not allow polished bearing areas and machined taper surfaces to come in contact with hard or abrasive surfaces, as scratching or in any way damaging these surfaces can significantly affect the structural integrity.
- Do not substitute another manufacture's device for any of the Howmedica Osteonics® Trident™ System components because design, material, or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together.
- Do not implant in obese patients because additional loading may lead to loss of fixation or device failure.
- Do not implant in patients undergoing revision of previously unsuccessful femoral head replacement, cup arthroplasty, or other procedure because the safety and effectiveness of these devices for indications other than non-inflammatory degenerative joint disease have not been established.
- Discard all damaged or mishandled implants. Never reuse an implant. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to early failure of the device.
- **Do not resterilize.** Return all packages with flaws in the sterile barrier to the supplier.

Precautions

- Clean bearing surfaces of debris prior to assembly as foreign particles may cause accelerated bearing wear, which may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Clean and dry machine taper surfaces to ensure proper seating and assembly.
- Do not handle the hydroxylapatite treated regions as it may compromise the sterility or integrity of the coating/implant interface.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load.
- Do not use a metal or zirconia head with the Howmedica Osteonics® Trident™ Alumina Insert as this may accelerate bearing wear and lead to early failure of the device.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Avoid excessive verticalization of the shell which may accelerate bearing wear.

Adverse Events (Clinical Study)

The adverse event information for the ceramic bearing Trident™ System is based on the clinical studies that were conducted for the ABC and Trident™ Systems. The Trident™ design was intended to address the adverse events related to the chipping of the ABC ceramic inserts during implantation. Due to the similarities in device and study design, two year adverse event rates for the Howmedica Osteonics® ABC System, as compared to the control system, are presented here in support of the safety of the Howmedica Osteonics® Trident™ System. Both hip systems feature identical ceramic-on-ceramic articulating bearing surfaces, except that the Trident™ System includes an additional larger size. Table 1 summarizes the operative site adverse events reported for the 349 cases implanted with the ABC System components (172 cases implanted with Howmedica Osteonics® PSL® MicroStructured® ABC Shells, referred to as ABC System I, and 177 cases implanted with the Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells, referred to as ABC System II) compared to 165 cases implanted with a control with a conventional polyethylene/metal bearing couple, evaluated out to 24 months postoperatively.

Table 2 summarizes the operative site adverse events reported for 185 cases implanted with the Howmedica Osteonics® Trident™ System compared to 349 cases implanted with the ABC System components (172 cases implanted with Howmedica Osteonics® PSL® MicroStructured® ABC Shells, referred to as ABC System I, and 177 cases implanted with the Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells, referred to as ABC System II) and 165 cases implanted with a control with a conventional polyethylene/metal bearing couple, evaluated out to 6 months postoperatively. Greater than 95% of cases implanted with ABC System I, ABC System II, and the control hip system had available six month data, whereas approximately 50% of the implanted Trident™ cases had available six month data at the time of data base closure. The adverse event rates for the Trident™ System were not significantly different from the other systems studied.

TABLE 1: Time Course Distribution of Operative Site Adverse Event Incidences for ABC System I¹ and ABC System II² vs. Control hip system out to 24 Months Post-Operatively.

| Operative Site Related | ABC SYSTEM I ¹ (172 cases enrolled) | | | | | | ABC SYSTEM II ² (177 cases enrolled) | | | | | | CONTROL (165 cases enrolled) | | | | | |
|-------------------------|---|-----|-----|-----|-----|-----|--|-----|-----|-----|-----|-----|---------------------------------|-----|-----|-----|-----|-----|
| | io | ea | 6 | 12 | 24 | Tot | io | ea | 6 | 12 | 24 | Tot | io | ea | 6 | 12 | 24 | Tot |
| Visit | 172 | 170 | 166 | 168 | 131 | | 177 | 177 | 167 | 173 | 129 | | 165 | 163 | 157 | 155 | 119 | |
| N = cases evaluated | | | | | | | | | | | | | | | | | | |
| Revision: | | | | 1 | | 1 | | | | | | | | 2 | | | | 2 |
| Femoral | | | | | | | | | | | | | | | | | | |
| Acetabular | | | | | | | | 1 | | | | 1 | | | | | 1 | 1 |
| Acetabular Insert | | | | | | | | 1 | | | | 1 | | 2 | | | 2 | 4 |
| Femoral Head | | | 1 | | | 1 | | 1 | | | | 1 | | 2 | | | 2 | 4 |
| All Components | | | | | | | | | | 1 | | 1 | | | | | | |
| Femoral Fracture/Crack | 6 | 3 | 1 | | | 10 | 7 | 2 | | | | 9 | 7 | 1 | 1 | | | 9 |
| Trochanteric Frac/Crack | 4 | | | | | 4 | 3 | | | | | 3 | 1 | | | | | 1 |
| Acetabular Frac/Crack | 2 | | | | | 2 | | | | | | | | | | | | |
| Loosening: Fem. Comp | | | | | | | | | | | | | | | | | | |
| Acetabular Comp | | | | | | | | | | | | | | | | | | |
| Both Comp | | | | | | | | | | | | | | | | | | |
| Superficial Infection | | 1 | | | | 1 | | 4 | | | | 4 | | 5 | | | | 5 |
| Deep Joint Infection | | | | | | | | | | 1 | | 1 | | 1 | | 1 | | 2 |
| Hematoma | | 2 | | | | 2 | | | | | | | | 1 | | | | 1 |
| Wound Related | | 8 | | | | 8 | | 8 | | | | 8 | 1 | 6 | | | | 7 |
| Dislocation: | | 4 | | | | 4 | | 5 | | | | 5 | 1 | 3 | | | 1 | 5 |
| Single | | | | | | | | 1 | | | | 1 | | 1 | | | | 2 |
| Recurrent | | | | | | | | 1 | | | | 1 | | | | | | |
| Nerve Palsy | 1 | | | | | 1 | | 1 | | | | | | | | | | |
| Subluxation | | | | | | | | | | | | | | | 1 | | | 1 |
| Excessive Hip Pain | 1 | 1 | | | | 2 | | | 1 | | | 1 | | | 2 | | | 2 |
| Bursitis | | 1 | 1 | 2 | 1 | 5 | | | 4 | 4 | | 8 | | 1 | 1 | 3 | | 5 |
| Heterotopic bone | | 3 | 2 | | | 5 | | 3 | 3 | | | 6 | | 6 | 4 | | | 10 |
| Subsidence | | | 1 | | | 1 | | 2 | | | | 2 | | | | | | |
| Trochanteric non-union | | | | | | | | | | | | | | | | | | |
| Soft Tissue Trauma | | 2 | 2 | 1 | | 5 | | | 1 | 5 | | 6 | | 1 | 1 | 3 | | 5 |
| Alumina Insert Chip | 4 | | | | | 4 | 4 | | | | | 4 | | | | | | |
| Miscellaneous | 2 | 5 | 3 | 2 | | 12 | 4 | 3 | 1 | 4 | | 12 | 3 | 6 | 2 | 3 | 2 | 16 |
| TOTAL | 20 | 28 | 10 | 8 | 2 | 68 | 18 | 32 | 10 | 15 | 0 | 75 | 13 | 38 | 12 | 11 | 8 | 82 |

io = intraoperatively; ea = early (7 weeks); 6 = 6 months; 12 = 12 months; 24 = 24 months postoperative; Tot = total

All cases enrolled in the ABC I, ABC II, and Control groups had at least 12 months postoperative follow-up at time of data base closure.

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells.

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TABLE 2: Time Course Distribution of Operative Site Adverse Event Incidences for the Trident™ System vs. ABC I, ABC II and Control hip systems out to Six Months Post-Operatively.

| Operative Site Related | ABC SYSTEM I ¹ (172 cases enrolled) | | | | ABC SYSTEM II ² (177 cases enrolled) | | | | TRIDENT* (185 enrolled) | | | | CONTROL (165 enrolled) | | | |
|-------------------------|---|-----|-----|-----|--|-----|-----|-----|----------------------------|-----|----|-----|---------------------------|-----|-----|-----|
| | io | ea | 6 | Tot | io | ea | 6 | Tot | io | ea | 6 | Tot | io | ea | 6 | Tot |
| N = cases evaluated | 172 | 170 | 166 | | 177 | 177 | 167 | | 185 | 178 | 97 | | 165 | 163 | 157 | |
| Revision: | | | | | | | | | | 1 | | 1 | | 2 | | 2 |
| Femoral | | | | | | | | | | | | | | | | |
| Acetabular | | | | | | 1 | | 1 | | | | | | | | |
| Acetabular Insert | | | | | | 1 | | 1 | | | | | | 2 | | 2 |
| Femoral Head | | | | | | 1 | | 1 | | 1 | | 1 | | 2 | | 2 |
| All Components | | | | | | | | | | | | | | | | |
| Femoral Fracture/Crack | 6 | 3 | 1 | 10 | 7 | 2 | | 9 | 3 | 1 | | 4 | 7 | 1 | 1 | 9 |
| Trochanteric Frac/Crack | 4 | | | 4 | 3 | | | 3 | 3 | | | 3 | 1 | | | 1 |
| Acetabular Frac/Crack | 2 | | | 2 | | | | | 2 | | | 2 | | | | |
| Loosening: Fem. Comp | | | | | | | | | | | | | | | | |
| Acetabular Comp | | | | | | | | | | | | | | | | |
| Both Comp | | | | | | | | | | | | | | | | |
| Superficial Infection | | 1 | | 1 | | 4 | | 4 | | 4 | | 4 | | 5 | | 5 |
| Deep Joint Infection | | | | | | | | | | | | | | 1 | | 1 |
| Hematoma | | 2 | | 2 | | | | | | 3 | | 3 | | 1 | | 1 |
| Wound Related | | 8 | | 8 | | 8 | | 8 | | 14 | | 14 | 1 | 6 | | 7 |
| Dislocation: Single | | 4 | | 4 | | 5 | | 5 | | 2 | | 2 | 1 | 3 | | 4 |
| Recurrent | | | | | | 1 | | 1 | | | | | | 1 | | 1 |
| Nerve Palsy | 1 | | | 1 | | 1 | | 1 | | | | | | | | |
| Subluxation | | | | | | | | | | | | | | | 1 | 1 |
| Excessive Hip Pain | 1 | 1 | | 2 | | | | 1 | 1 | 1 | 1 | 2 | | 2 | | 2 |
| Bursitis | | 1 | 1 | 2 | | | | 4 | 4 | 3 | 1 | 4 | | 1 | 1 | 2 |
| Heterotopic bone | | 3 | 2 | 5 | | 3 | | 3 | 6 | 5 | | 5 | | 6 | 4 | 10 |
| Subsidence | | | 1 | 1 | | 2 | | 2 | | | | | | | | |
| Trochanteric non-union | | | | | | | | | | | | | | | | |
| Soft Tissue Trauma | | | 2 | 2 | | | | 1 | 1 | 1 | 1 | 2 | | 1 | 1 | 2 |
| Alumina Insert Chip | 4 | | | 4 | | 4 | | 4 | | | | | | | | |
| Miscellaneous | 2 | 5 | 3 | 10 | 4 | 3 | 1 | 8 | 2 | 4 | 4 | 10 | 3 | 6 | 2 | 11 |
| TOTAL | 20 | 28 | 10 | 58 | 18 | 32 | 10 | 60 | 10 | 40 | 7 | 57 | 13 | 38 | 12 | 63 |

io = intraoperatively; ea = early (7 weeks); 6 = 6 months postoperative; Tot = total

All cases enrolled in the ABC I, ABC II, and Control groups had at least 12 month postoperative follow-up at time of data base closure

* 103 cases out to 6 months postoperative follow-up at time of data base closure

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

Other Potential Adverse Events

The following list includes other potential adverse events that may also occur and were either reported in the studies or are generally reported in the literature for total hip replacement procedures:

- Pulmonary embolism
- Circulatory compromise
- Vascular disorders, including thrombus
- Bronchiopulmonary disorders, including emboli
- Myocardial infarction
- Death
- Urinary tract infection
- Genitourinary disorders
- Gastrointestinal disorders
- Peripheral neuropathies
- Nerve damage
- Localized progressive bone resorption (osteolysis)
- Loosening of total hip components
- Pain due to loosening of the implant components.
- Metal sensitivity reactions
- Dermatologic disorders
- Carcinoma
- Heterotopic bone formation
- Reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb
- Breakage of the ceramic insert or ceramic head
- Disassembly of modular components at the taper junctions

Clinical Results

Two groups were studied. Due to the similarities in device and study design, two year clinical results for the Howmedica Osteonics® ABC Ceramic System, and early (up to six month) clinical data for the Trident™ System as compared to the ABC and control hip systems, were evaluated. In addition, pre-clinical testing on the Trident™ System was compared to the ABC and control hip systems.

The following table provides a comparison of the demographics of those patients who received the Trident™, ABC, and control hip systems, respectively.

Table 3: Patient Demographics for the Trident™, ABC, and Control System Study Groups

| Category | TRIDENT | ABC SYSTEM I ¹ | ABC SYSTEM II ² | CONTROL |
|--------------------|---------|---------------------------|----------------------------|---------|
| No. Cases | 185 | 172 | 177 | 165 |
| Male/female | 125/60 | 114/58 | 113/64 | 99/66 |
| Mean Age (yrs.) | 51.8 | 53.1 | 53.1 | 53.3 |
| Mean Weight (lbs.) | 192.3 | 186.7 | 191.8 | 188.5 |
| Mean Height (ins.) | 68.6 | 68.6 | 68.2 | 68.4 |

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

ABC System Study

The effectiveness of the Howmedica Osteonics® ABC System ceramic components (ABC System I included all cases implanted with Howmedica Osteonics® PSL® MicroStructured® ABC Shells, ABC System II included all cases implanted with the Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells) was determined through the analysis

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of the Harris Hip Scores (HHS) and radiographic measurements. Table 4 compares the mean total Harris Hip Scores, and the percentage of cases with a minimum HHS of 70 and a Good/Excellent Rating of at least 80, as well as the radiographic success rates for the investigational and control groups, at two years postoperatively.

TABLE 4: Primary Efficacy Assessments for ABC System I and ABC System II vs. Control System. Efficacy assessment based on mean Harris Hip Score (HHS) and radiographic success reported for those cases with 2 year follow-up data.

| Primary Efficacy Assessment | ABC SYSTEM I 140 cases enrolled | ABC SYSTEM II 140 cases enrolled | CONTROL 133 cases enrolled |
|--|------------------------------------|-------------------------------------|-------------------------------|
| Preoperative mean HHS (range) | 49.6 (19.3 - 89.6) n=126 | 49.0 (24.7 - 75.2) n=131 | 49.3 (21.4 - 87.3) n=125 |
| 2 year postop mean HHS (range) | 96.3 (48.0 - 100) n=122 | 96.9 (56.9 - 100) n=120 | 95.1 (58.8 - 100) n=110 |
| % Excellent/Good Results (HHS 80-100 points) at 2 years postop | 95.9% (117/122) | 96.7% (116/120) | 93.6% (103/110) |
| % Total HHS \geq 70 at 2 years postop | 98.4% (120/122) | 99.2% (119/120) | 98.2% (108/110) |
| % Radiographic Success at 2 years postop | 100% (123/123) | 99.2% (121/122) | 100% (113/113) |

n = number of cases that had evaluable data

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

Table 5 summarizes the two year success rates as they relate to the success/failure criteria of the ABC System study. For the purposes of the study, a patient was considered a success if they met all seven of the criteria identified in the table. Success for the study required that the patient success rates for the ABC System were no more than 7.5 percentage points worse than those of the control hip system and achieving complication rates that were statistically no worse than the control hip system at two years postoperatively.

TABLE 5: 2 Year Patient Success Rates for ABC System

| Patient Success Criteria | ABC SYSTEM I ¹ 140 cases enrolled | ABC SYSTEM II ² 140 cases enrolled | CONTROL 133 cases enrolled |
|---|---|--|-------------------------------|
| Absence of Revision (%) | 139 / 140 (99.3%) | 138 / 140 (98.6%) | 128 / 133 (96.2%) |
| Total HHS \geq 70 | 120 / 122 (98.4%) | 119 / 121* (98.4%) | 117 / 120** (97.5%) |
| Acetabular RLL \leq 2mm | 122 / 122 (100%) | 120 / 120 (100%) | 112 / 112 (100%) |
| Acetabular Migration \leq 3mm | 122 / 122 (100%) | 120 / 120 (100%) | 112 / 112 (100%) |
| Wear Acetabular Insert <0.5 mm/yr | 122 / 122 (100%) | 120 / 120 (100%) | 112 / 112 (100%) |
| Femoral RLL \leq 2mm | 118 / 118 (100%) | 115 / 115 (100%) | 110 / 110 (100%) |
| Progressive Femoral Component Subsidence \leq 5mm | 122 / 122 (100%) | 119 / 120 (99.2%) | 111 / 111 (100%) |
| Patient Success Rate | 97.5% (118/121) | 95.8% (115/120) | 93.2% (110/118) |

* One case with HHS <70 at 12 months, and no 24 month follow-up and is included

** One case, with HHS <70 at 12 months, died before 24 month follow-up and is included

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

Trident System Study

The Howmedica Osteonics® Trident™ study design is a prospective, non-randomized historically controlled, multicenter clinical trial. The total study group was approved for 213 cases diagnosed with non-inflammatory degenerative joint disease (NIDJD). The available Trident™ System data were compared to the ABC System I, ABC System II, and control group data collected in the Howmedica Osteonics® ABC System study. Six month clinical data was available on 97 Trident cases.

The effectiveness of the Howmedica Osteonics® Trident™ System was determined through the analysis of the Harris Hip Scores (HHS). Table 6 compares the mean total Harris Hip Scores of the Trident™, ABC System I, ABC System II, and control hip system at the early six month postoperative interval.

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TABLE 6: Time Course Distribution Table that compares early effectiveness data (mean Harris Hip Score - HHS) of the Trident™ System to the ABC System I, ABC System II, and Control hip system data.

| Summary of Effectiveness Data | ABC SYSTEM I ¹ | | | ABC SYSTEM II ² | | | TRIDENT | | | CONTROL | | |
|-------------------------------|---------------------------|---------|----------|----------------------------|---------|----------|---------|---------|----------|---------|---------|----------|
| Visit | Pre-Op | 7 weeks | 6 months | Pre-Op | 7 weeks | 6 months | Pre-Op | 7 weeks | 6 months | Pre-Op | 7 weeks | 6 months |
| N=evaluable cases | 170 | 162 | 162 | 176 | 177 | 166 | 184 | 175 | 97 | 165 | 160 | 156 |
| HHS | 48.3 | 78.6 | 93.2 | 48.7 | 79.2 | 94.7 | 47.5 | 80.3 | 95.4 | 48.9 | 77.3 | 91.7 |
| (Std) | (13.0) | (11.4) | (9.6) | (10.7) | (13.1) | (7.8) | (11.7) | (9.8) | (7.4) | (12.3) | (10.1) | (10.7) |

¹ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; ²ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

Sterilization

- These components have been sterilized by gamma radiation.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
- If the package is opened, but the product is not used, the component **must not** be resterilized and must be discarded or returned to the supplier.
- **Do NOT autoclave ceramic heads or ceramic inserts, especially when they are affixed to their mating components. Differing expansion rates could cause ceramic to break or crack. Do NOT autoclave, and then rapidly cool, a ceramic component. Non-adherence to these warnings can permanently compromise the mechanical and structural integrity of the ceramic components.**

CAUTION: Federal law (U.S.A.) restricts this device
to sale by or on the order of a licensed
physician.

Osteonics® and Crossfire® are registered trademarks of Howmedica Osteonics Corp.
Secur-Fit™ and Trident™ are trademarks of Howmedica Osteonics Corp.

Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677

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Patient Labeling Secur-Fit™ ABC Ceramic Acetabular System

PATIENT PRODUCT INFORMATION

Howmedica Osteonics Secur-Fit™ ABC Ceramic Acetabular System

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3. How is a total hip replacement performed?
4. What other ways can a damaged hip joint be treated?
5. What is the Howmedica Osteonics Secur-Fit™ ABC Ceramic Acetabular System?
6. What are the benefits of the Howmedica Osteonics Secur-Fit™ ABC Ceramic Acetabular System?
7. What are the possible complications of total hip replacement and the Secur-Fit ABC Ceramic Acetabular System?
8. What else should I know about total hip replacement?

Glossary of Terms

Adverse: Harmful or unfavorable.

Anesthetic: Drug used to eliminate the feeling of pain.

Artificial: Man-made.

Brittle: Easily broken, cracked or shattered.

Cortisone: Steroid used especially in the treatment of rheumatoid arthritis.

Debris: An accumulation of foreign material.

Fixation: The stabilization of fractured bony parts.

Friction: The act of rubbing.

Fusion: Uniting or bringing together.

Intra-operative: During surgery.

Invasive: Involving entry into the body through incision of the skin or insertion of an instrument.

Latent: Potential for development, though currently inactive.

Lubrication: To make smooth or slippery.

Mortality: The number of deaths in a given time or place.

Osteotomy: The removal of a wedge of bone to improve alignment.

Post-Operative: Following surgery.

Pre-Operative: Before surgery.

Revision: Replacement of a failed implant with a new implant.

Skeletal Immaturity: Bones lacking complete growth or development.

Subsidence: To sink or settle down.

Wear Resistance: Able to withstand deterioration.

1. What are the reasons for total hip replacement?

Total hip replacement is often reserved for patients who:

- have a painful, disabling joint disease of the hip resulting from a severe form of arthritis
- are not likely to achieve satisfactory results from less invasive procedures, such as arthrodesis (artificial stiffening or fixation of the joint)
- have bone stock that is poor quality or inadequate for other reconstructive techniques.

Patient Labeling Secur-Fit™ ABC Ceramic Acetabular System

2. Are there any reasons why I should not have a total hip replacement?

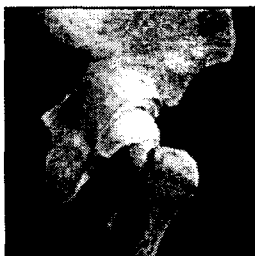
Total hip replacement is not recommended under the following conditions:

- The patient has any active or suspected latent infection in or about the hip joint
- The patient is unable to follow the pre-operative or post-operative schedule required for success with this implant.
- There is not enough bone to support fixation of the implants
- Skeletal immaturity

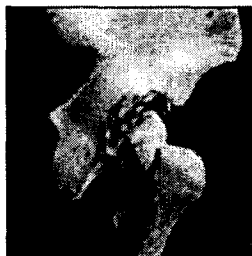
3. How is a total hip replacement performed?

In a total hip replacement operation, the surgeon replaces the worn surfaces of the hip joint with an artificial hip joint. The worn head of the femur (thighbone) is replaced with a metal or ceramic ball mounted on a stem; the stem is placed firmly into the canal of the thighbone at its upper end. The acetabulum (hip socket) is prepared and implanted with a metal cup and plastic or ceramic insert. The cup is placed firmly into the socket of the pelvis. The cup and stem are attached to each other by a ball and socket type bearing structure called the insert (which attaches to the cup) and head (which attaches to the stem).

All components of the artificial hip joint are made of standard materials that have a long history of use in the human body. The cup and stem may have a coating on the surface, which is intended to allow bone to grow into it in order to hold the cup and stem in place.



Normal Hip



Diseased Hip



Replaced Hip

4. What other ways can a damaged hip joint be treated?

Your doctor should discuss with you other procedures that may treat your condition. These include:

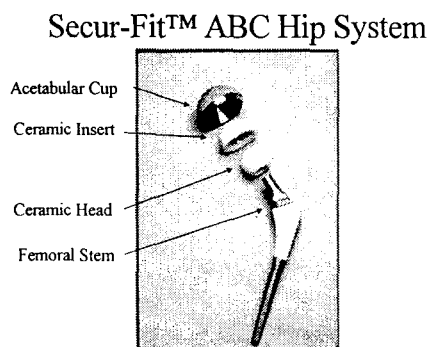
- Conservative, non-surgical treatment, such as activity modification, weight reduction, pain medication, physical therapy, cortisone injections, and walking aids
- Hip osteotomy
- Hip fusion
- A total hip replacement with plastic/ceramic, plastic/metal, or metal/metal bearing surfaces

After discussing the above options with your doctor, you may decide to have no treatment at all at the present time.

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5. What is the Howmedica Osteonics Secur-Fit™ ABC Ceramic Acetabular System?

The Secur-Fit™ ABC Ceramic System consists of components of an artificial hip joint. While current artificial hip systems use a plastic insert and a ceramic or metal head, or a metal insert and a metal head, the insert and head of the Secur-Fit™ ABC Ceramic Acetabular System are both made of alumina ceramic (aluminum oxide).



6. Why should I choose the Howmedica Osteonics Secur-Fit™ ABC Ceramic Acetabular System?

Laboratory testing of ceramics has shown them to be biocompatible (tolerated well by healthy tissues in the body), hard, have a good surface finish, inert (non-reactive) and have excellent lubrication, friction and wear properties.

Safety and Effectiveness

A 2-year well-controlled clinical study to evaluate the safety and effectiveness of the Howmedica Osteonics ABC Ceramic Acetabular System was performed at orthopaedic centers of excellence across the United States. Three hundred forty-nine cases who required a total hip replacement received the Howmedica Osteonics ABC Ceramic Acetabular System (MicroStructured® ABC System I [172 cases] or Secur-Fit™ ABC System II [177 cases]) compared to 165 cases who received the control system with a conventional polyethylene insert and metal head. The Secur-Fit™ ABC Ceramic Acetabular System (ABC System II) featured a metal acetabular cup with a coating of hydroxyapatite ceramic, while the metal cup of the MicroStructured® ABC Ceramic Acetabular System (ABC System I) featured a porous coating of metal beads. They were evaluated for up to 24 months following surgery.

Safety for the Secur-Fit™ ABC Ceramic Acetabular System was evaluated based on a comparison of the adverse event rates with those of the control system. The adverse event rates were comparable for both systems. There were no deaths associated with the total hip replacement procedure (0% mortality) and only 2 cases out of the original 177 (1.1 %) cases implanted with the Secur-Fit™ ABC Ceramic Acetabular System components needed additional surgery to revise or remove the implanted components. One case had the acetabular cup, ceramic insert and ceramic femoral head revised five days after surgery due to recurrent dislocation of the components. The other case had all components removed ten months after surgery due to an infection in the hip joint. The most common reasons for revision or removal of any total hip joint prosthesis are typically due to:

- loosening of the femoral or acetabular components
- infection

Patient Labeling Secur-Fit™ ABC Ceramic Acetabular System

- recurrent dislocation of components
- fracture or breakage of the components
- excessive wear of implant surfaces

The hardness and strength of the ceramic material makes it attractive for use in orthopaedic-implants. Nevertheless, due to the brittle nature of ceramics, there is a potential for sudden breakage of the ceramic components, and chipping of the ceramic insert during the implantation procedure. While there were no component breakages reported during the course of this study, there was a 3.4% rate of ceramic insert chipping reported to have occurred during surgery (16/464 cases; which includes all 349 cases in the original ABC System study and 115 implanted in continuing enrollment by study surgeons). The insert chipping rate for cases implanted with the Secur-Fit™ ABC Ceramic Acetabular System components was 3.8% (11/289). In each case the chipped insert was replaced with another ceramic insert during the same surgical procedure and all cases healed uneventfully. If the insert is chipped during surgery, the surgeon is instructed to remove the chipped insert and cup and replace them with new components.

Howmedica Osteonics evaluated the effectiveness of the Howmedica Osteonics® ABC Ceramic Acetabular System through the analysis of 280 study cases (140 ABC System I and 140 ABC System II) and 133 control cases that had two year clinical results. The primary effectiveness measurement used to evaluate relief from pain and return to normal function was the Harris Hip Score (HHS). Radiographic (x-ray) measurements were also taken to measure the stability of the components. A patient's Total Harris Hip Score was based on 10 items, including pain, support, distance walked, and range of motion. The largest possible score (100) indicates pain relief and normal functional ability; the smallest score (0) indicates severe pain and disability. A score <70 was considered failing.

The average Harris Hip Scores two years after surgery for ABC System I, ABC System II, and the control system were 96, 97 and 95, respectively. The percentage of cases with scores greater than 70 were 98%, 99%, and 98%, respectively. The percentage of cases considered to have radiographic success two years after surgery were 100%, 99.2%, and 100%, respectively, for the three systems studied. Among patients who received the Secur-Fit™ ABC Ceramic Acetabular System (ABC System II) only 1 case (0.8%) was determined to have an unstable (potentially loose) implant, based on the x-ray evaluations.

A patient success was defined at 2 years after surgery as having the hip replacement system still in place, having a Harris Hip Score of greater than 70 points, and having the absence of any x-ray signs which might indicate the hip replacement was loose or unstable. Patient success rates and adverse event rates were compared to the control group to determine the successful outcome of the study. Study success for the ABC System(s) required that the patient success rates were not significantly worse than the control, and that complication rates were not statistically worse than the control, at two years after surgery. The 2-year patient success rates for ABC System I, ABC System II, and the control system are provided in the table below.

TABLE: 2 Year Patient Success Rates

| ABC SYSTEM I | ABC (Secure-Fit) SYSTEM II | CONTROL |
|---------------------|-----------------------------------|--------------------|
| 140 cases enrolled | 140 cases enrolled | 133 cases enrolled |
| 97.5% | 95.8% | 93.2% |
| (n=121) | (n=120) | (n=118) |

n=number of evaluable cases

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7. What are the possible complications of total hip replacement and the Secur-Fit™ ABC Ceramic Acetabular System?

Possible complications specific to the Secur-Fit™ ABC Ceramic Acetabular System are:

- Intra-operative chipping of the Secur-Fit™ ABC ceramic insert.
- Sudden breakage of the ceramic components as a result of excessive forces placed on the components. Breakage of these components will require additional surgery to revise and/or replace them.

Possible complications of any artificial hip replacement are:

- dislocation
- loosening
- breakage of the implants
- fracture of the bone surrounding the implant
- reaction to the implant's materials
- bone loss
- change in the length of the treated leg
- pain
- stiffness in the hip
- excessive bleeding
- fusion of the hip joint
- nerve damage
- allergic reaction to medical and/or blood transfusion
- infection
- anesthetic reactions
- blood clots in the legs and/or lungs
- amputation
- heart attack
- pneumonia
- excessive wear of the implant's components
- decrease of bone mass
- in rare instances, death

Call your doctor if you experience any of the following symptoms;

- Redness, burning, swelling, or drainage from your operated area
- Fever of 100 degrees or higher
- Pain that does not lessen with rest
- Acute, severe pain in the hip associated with twisting, turning or injury

Please ask your surgeon to discuss with you any of the above complications that are not familiar to you.

8. What else should I know about total hip replacement?

Consult your doctor regarding pre-operative considerations, post-operative rehabilitation, and expectations for surgery. It is important to begin planning for your return home from the hospital before your surgical procedure. Your surgeon may suggest tips to prepare your home for after surgery. For example, get an apron or belt with pockets to carry things while you are on crutches, buy or borrow a cordless phone, remove scatter rugs and other obstacles to safe transport using crutches, have high chair and commode accessories available. Above all, during

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this time, treat yourself well, eat balanced meals, get plenty of rest, and if requested by your surgeon, donate your own blood so it can be transfused during and after surgery.

Because you will need to rest your hip properly, your post-surgical activities are limited. During the first weeks after surgery, you may be advised to put a pillow between your legs when turning over in bed, wear elastic stockings, use raised toilet seat, take showers rather than baths, restrict activities such as sudden twisting or turning, crossing legs, exposing the scar to sunlight, and driving.

- Total hip implants have limitations. For example, extreme forces placed on the implants through excessive patient weight or activities, such as running and jumping, can affect the artificial joint. Patients should govern their activities accordingly.
- The artificial hip joint will not restore function to the same level as normal, healthy bone and the patient should not have unrealistic expectations.
- The life span of the artificial hip joint components is difficult to estimate, however it cannot be expected to equal that of normal, healthy bone.
- The components of the artificial hip joint are affected by many biological and mechanical factors, which cannot be determined ahead of time.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may result in a need for additional surgeries, including revision or removal of the implants.

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7. What are the possible complications of total hip replacement and the Trident™ Ceramic Acetabular System?
8. What else should I know about total hip replacement?

Glossary of Terms

Adverse: Harmful or unfavorable.

Anesthetic: Drug used to eliminate the feeling of pain.

Artificial: Man-made.

Brittle: Easily broken, cracked or shattered.

Cortisone: Steroid used especially in the treatment of rheumatoid arthritis.

Debris: An accumulation of foreign material.

Fixation: The stabilization of fractured bony parts.

Friction: The act of rubbing.

Fusion: Uniting or bringing together.

Intra-operative: During surgery.

Invasive: Involving entry into the body through incision of the skin or insertion of an instrument.

Latent: Potential for development, though currently inactive.

Lubrication: To make smooth or slippery.

Mortality: The number of deaths in a given time or place.

Osteotomy: The removal of a wedge of bone to improve alignment.

Post-Operative: Following surgery.

Predecessor: One that comes before another.

Pre-Operative: Before surgery.

Revision: Replacement of a failed implant with a new implant.

Skeletal Immaturity: Bones lacking complete growth or development.

Subsidence: To sink or settle down.

Wear Resistance: Able to withstand deterioration.

1. What are the reasons for total hip replacement?

Total hip replacement is often reserved for patients who:

- have a painful, disabling joint disease of the hip resulting from a severe form of arthritis
- are not likely to achieve satisfactory results from less invasive procedures, such as arthrodesis (artificial stiffening or fixation of the joint)
- have bone stock that is poor quality or inadequate for other reconstructive techniques.

Patient Labeling Trident™ Ceramic Acetabular System

2. Are there any reasons why I should not have a total hip replacement?

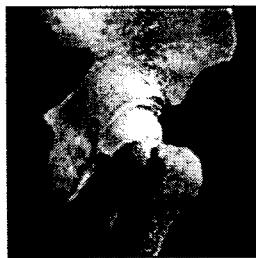
Total hip replacement is not recommended under the following conditions:

- The patient has any active or suspected latent infection in or about the hip joint
- The patient is unable to follow the pre-operative or post-operative schedule required for success with this implant.
- There is not enough bone to support fixation of the implants
- Skeletal immaturity

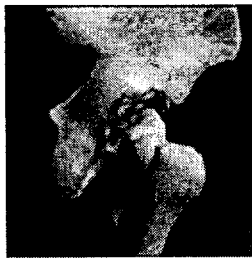
3. How is a total hip replacement performed?

In a total hip replacement operation, the surgeon replaces the worn surfaces of the hip joint with an artificial hip joint. The worn head of the femur (thighbone) is replaced with a metal or ceramic ball mounted on a stem; the stem is placed firmly into the canal of the thighbone at its upper end. The acetabulum (hip socket) is prepared and implanted with a metal cup and plastic or ceramic insert. The cup is placed firmly into the socket of the pelvis. The cup and stem are attached to each other by a ball and socket type bearing structure called the insert (which attaches to the cup) and head (which attaches to the stem).

All components of the artificial hip joint are made of standard materials that have a long history of use in the human body. The cup and stem may have a coating on the surface, which is intended to allow bone to grow into it in order to hold the cup and stem in place.



Normal Hip



Diseased Hip



Replaced Hip

4. What other ways can a damaged hip joint be treated?

Your doctor should discuss with you other procedures that may treat your condition. These include:

- Conservative, non-surgical treatment, such as activity modification, weight reduction, pain medication, physical therapy, cortisone injections, and walking aids
- Hip osteotomy
- Hip fusion
- A total hip replacement with plastic/ceramic, plastic/metal, or metal/metal bearing surfaces

After discussing the above options with your doctor, you may decide to have no treatment at all at the present time.

5. What is the Howmedica Osteonics Trident™ Ceramic Acetabular System?

The Trident™ Ceramic Acetabular System includes the components of an artificial hip joint. While current artificial hip systems use a plastic insert with a ceramic or metal head, or a metal insert with a metal head, the insert and head of the Trident™ Ceramic Acetabular System are made of alumina ceramic (aluminum oxide). The ceramic insert has a metal 'sleeve' or cap that is permanently fixed to its outer surface. The ceramic insert (and sleeve) mate with a metal acetabular cup that is coated with an hydroxyapatite ceramic.

6. Why should I choose the Howmedica Osteonics Trident™ Ceramic Acetabular System?

Laboratory testing of ceramics have shown them to be biocompatible (tolerated well by healthy tissues in the body), hard, have a good surface finish, inert (non-reactive) and have excellent lubrication, friction and wear properties.

Safety and Effectiveness

A 2-year well-controlled clinical study to evaluate the safety and effectiveness of the Howmedica Osteonics ABC Ceramic Acetabular System was performed at orthopaedic centers of excellence across the United States. Three hundred forty-nine cases who required a total hip replacement received the Howmedica Osteonics ABC Ceramic Acetabular System (MicroStructured® ABC System I [172 cases] or Secur-Fit™ ABC System II [177 cases]) compared to 165 cases who received the control system with a conventional polyethylene insert and metal head. The Secur-Fit™ ABC Ceramic Acetabular System (ABC System II) featured a metal acetabular cup with a coating of hydroxyapatite ceramic, while the metal cup of the MicroStructured® ABC Ceramic Acetabular System (ABC System I) featured a porous coating of metal beads. They were evaluated for up to 24 months following surgery. The Trident™ components were added later in the study to address potential chipping of the ABC System I and System II ceramic inserts during the implantation procedure. One hundred eighty five Trident™ cases have been implanted and evaluated for up to 6 months following surgery.

Secur-Fit™ ABC Ceramic Acetabular System Study Results:

Safety for the Secur-Fit™ ABC Ceramic Acetabular System was evaluated based on a comparison of the adverse event rates with those of the control system. The adverse event rates were comparable for both systems. There were no deaths associated with the total hip replacement procedure (0% mortality) and only 2 cases out of the original 177 (1.1 %) cases implanted with the Secur-Fit™ ABC Ceramic Acetabular System components needed additional surgery to revise or remove the implanted components. One case had the acetabular cup, ceramic insert and ceramic femoral head revised five days after surgery due to recurrent dislocation of the components. The other case had all components removed ten months after surgery due to an infection in the hip joint. The most common reasons for revision or removal of any total hip joint prosthesis are typically due to:

- loosening of the femoral or acetabular components
- infection
- recurrent dislocation of components
- fracture or breakage of the components
- excessive wear of implant surfaces

The hardness and strength of the ceramic material makes it attractive for use in orthopaedic implants. Nevertheless, due to the brittle nature of ceramics, there is a potential for sudden breakage of the ceramic components, and chipping of the ceramic insert during the implantation procedure. While there were no component breakages reported during the course of this study, there was a 3.4% rate of ceramic insert chipping reported to have occurred during surgery (16/464 cases; which includes all 349 cases in the original ABC System study and 115 implanted in continuing enrollment by study surgeons). The insert chipping rate for cases implanted with the Secur-Fit™ ABC Ceramic Acetabular System components was 3.8% (11/289). In each case the chipped insert was replaced with another ceramic insert during the same surgical procedure and all cases healed uneventfully. If the insert is chipped during surgery, the surgeon is instructed to remove the chipped insert and cup and replace them with new components.

Howmedica Osteonics evaluated the effectiveness of the Howmedica Osteonics® ABC Ceramic Acetabular System through the analysis of 280 study cases (140 ABC System I and 140 ABC System II) and 133 control cases that had two year clinical results. The primary effectiveness measurement used to evaluate relief from pain and return to normal function was the Harris Hip Score (HHS). Radiographic (x-ray) measurements were also taken to measure the stability of the components. A patient's Total Harris Hip Score was based on 10 items, including pain, support, distance walked, and range of motion. The largest possible score (100) indicates pain relief and normal functional ability; the smallest score (0) indicates severe pain and disability. A score <70 was considered failing.

The average Harris Hip Scores two years after surgery for ABC System I, ABC System II, and the control system were 96, 97 and 95, respectively. The percentage of cases with scores greater than 70 were 98%, 99%, and 98%, respectively. The percentage of cases considered to have radiographic success two years after surgery were 100%, 99.2%, and 100%, respectively, for the three systems studied. Among patients who received the Secur-Fit™ ABC Ceramic Acetabular System (ABC System II) only 1 case (0.8%) was determined to have an unstable (potentially loose) implant, based on the x-ray evaluations.

A patient success was defined at 2 years after surgery as having the hip replacement system still in place, having a Harris Hip Score of greater than 70 points, and having the absence of any x-ray signs which might indicate the hip replacement was loose or unstable. Patient success rates and adverse event rates were compared to the control group to determine the successful outcome of the study. Study success for the ABC System(s) required that the patient success rates were not significantly worse than the control, and that complication rates were not statistically worse than the control, at two years after surgery. The 2-year patient success rates for ABC System I, ABC System II, and the control system are provided in the table below.

TABLE: 2 Year Patient Success Rates

| ABC SYSTEM I | ABC (Secure-Fit) SYSTEM II | CONTROL |
|---------------------|-----------------------------------|--------------------|
| 140 cases enrolled | 140 cases enrolled | 133 cases enrolled |
| 97.5% | 95.8% | 93.2% |
| (n=121) | (n=120) | (n=118) |

n=number of evaluable cases

Trident™ Ceramic Acetabular System Study Results:

The same clinical study evaluated the safety of the Trident™ Ceramic Acetabular System. Adverse event rates for the 185 cases implanted with Trident™ components, 177 cases implanted with ABC System I, 172 cases implanted with the ABC System II, and 165 cases implanted with the control system were evaluated at comparable (2.5 months) time frames. Chipping of the ceramic inserts was not detected in a single Trident™ case. Otherwise, the adverse event rates were comparable for all systems. There were no deaths associated

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Patient Labeling Trident™ Ceramic Acetabular System

with the total hip replacement procedure (0% mortality) and only 1 Trident™ case (0.5%) required additional surgical intervention (revision of one of the components) due to a femoral fracture.

Howmedica Osteonics evaluated the effectiveness of the Trident™ System (97 cases) at 6 months after surgery and compared the results to the ABC System I (162 cases), ABC System II (166 cases), and control system (156 cases). The primary effectiveness measurement used to evaluate relief from pain and return to normal function was the Harris Hip Score (HHS). A score <70 was considered failing. Radiographic (x-ray) measurements, taken to measure the stability of the components, were not included in this analysis due to the short-term study follow-up on the Trident™ System. However, due to similarities in material, shape, and size, the Trident™ and ABC System devices are expected to demonstrate similar radiographic results.

The average Harris Hip Scores 6-months after surgery for the Trident™ System, ABC System I, ABC System II, and the control system were 95.4, 93.2, 94.7, and 91.7, respectively.

7. What are the possible complications of total hip replacement and the Trident™ Ceramic Acetabular System?

Possible complications specific to the Trident™ Ceramic Acetabular System are:

- Sudden breakage of the ceramic components as a result of excessive forces placed on the components. Breakage of these components will require additional surgery to revise and/or replace them.
- While it has not been demonstrated clinically, there is a potential for corrosion (eating away) where the metal sleeve on the ceramic insert touches other components of the implant system. Laboratory tests have shown this potential to be minimal.

Possible complications of any artificial hip replacement are:

- dislocation
- loosening
- breakage of the implants
- fracture of the bone surrounding the implant
- reaction to the implant's materials
- bone loss
- change in the length of the treated leg
- pain
- stiffness in the hip
- excessive bleeding
- fusion of the hip joint
- nerve damage
- allergic reaction to medical and/or blood transfusion
- infection
- anesthetic reactions
- blood clots in the legs and/or lungs
- amputation
- heart attack
- pneumonia
- excessive wear of the implant's components
- decrease of bone mass
- in rare instances, death

Patient Labeling Trident™ Ceramic Acetabular System

Call your doctor if you experience any of the following symptoms;

- . Redness, burning, swelling, or drainage from your operated area
- . Fever of 100 degrees or higher
- . Pain that does not lessen with rest
- . Acute, severe pain in the hip associated with twisting, turning or injury

Please ask your surgeon to discuss with you any of the above complications that are not familiar to you.

8. What else should I know about total hip replacement?

Consult your doctor regarding pre-operative considerations, post-operative rehabilitation, and expectations for surgery. It is important to begin planning for your return home from the hospital before your surgical procedure. Your surgeon may suggest tips to prepare your home for after surgery. For example, get an apron or belt with pockets to carry things while you are on crutches, buy or borrow a cordless phone, remove scatter rugs and other obstacles to safe transport using crutches, have high chair and commode accessories available. Above all, during this time, treat yourself well, eat balanced meals, get plenty of rest, and if requested by your surgeon, donate your own blood so it can be transfused during and after surgery.

Because you will need to rest your hip properly, your post-surgical activities are limited. During the first weeks after surgery, you may be advised to put a pillow between your legs when turning over in bed, wear elastic stockings, use raised toilet seat, take showers rather than baths, restrict activities such as sudden twisting or turning, crossing legs, exposing the scar to sunlight, and driving.

- Total hip implants have limitations. For example, extreme forces placed on the implants through excessive patient weight or activities, such as running and jumping, can affect the artificial joint. Patients should govern their activities accordingly.
- The artificial hip joint will not restore function to the same level as normal, healthy bone and the patient should not have unrealistic expectations.
- The life span of the artificial hip joint components is difficult to estimate, however it cannot be expected to equal that of normal, healthy bone.
- The components of the artificial hip joint are affected by many biological and mechanical factors, which cannot be determined ahead of time.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may result in a need for additional surgeries, including revision or removal of the implants.